

JUN - 6 2012

## Section 11. 510(k) Summary

### 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K120712

1. Submitter's Identification:

TaiDoc Technology Corporation

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Date of submission: March 6<sup>th</sup>, 2012

2. Device name:

Proprietary name: FORA ComfortScan Ear Thermometer

Regulatory information:

A. Regulation section: 21 CFR 880.2910

B. Classification: Class II

C. Product Code: FLL, Clinical electronic thermometer

D. Panel: General Hospital (80)

3. Intended Use:

The FORA ComfortScan Ear Thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages for home and professional use.

4. Device Description:

FORA ComfortScan Ear Thermometer is characterized by measuring human body temperature from the ear canal. It utilizes infrared technology to measure infrared energy emitted from eardrum tissue when making a temperature measurement.

Substantial Equivalence Information:

A. Predicate device name:

FORA ComfortScan Ear Thermometer, model TD-1261

B. Predicate K number: K081445

C. Comparison with predicate:

The modified FORA ComfortScan Ear Thermometer has the following similarities to the predicate device:

- Same operating principle.
- Same functions and physical appearance.
- Same fundamental scientific technology.
- Incorporate the same basic circuit design.
- Incorporate the same materials.
- Same shelf life.
- Same user interface and software.
- Packaged using the same materials.
- Manufactured by the same process.

The modifications:

- The intended use is expanded to for home and professional use.
- Labeling changes due to the modified indications.

5. Test Principle:

The thermometer measures temperature by reading infrared radiation emitting from eardrum tissue and converts it into a temperature value.

6. Performance Characteristics:

FORA ComfortScan Ear Thermometer has the same performance characteristics as the predicate device.

The performance of the FORA ComfortScan Ear Thermometer in the lab and clinical accuracy report demonstrated that the meter is safe and effective for home and professional use.

Software verification and validation, and risk analysis tests specific to user population change confirmed that the performance, safety and effectiveness of the FORA ComfortScan Ear Thermometer are equivalent to the predicate device.

7. Conclusion:

Based on the information provided in this submission, the FORA ComfortScan Ear Thermometer is substantially equivalent to the predicate FORA ComfortScan Ear Thermometer, model TD-1261.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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China 248

JUN - 6 2012

Re: K120712  
Trade/Device Name: FORA ComfortScan Ear Thermometer  
Regulation Number: 21 CFR 880.2910  
Regulation Name: Clinical Electronic Thermometer  
Regulatory Class: II  
Product Code: FLL  
Dated: March 6, 2012  
Received: March 8, 2012

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Section 8. Indications for Use

### Indications for Use

510(k) Number:

Device Name: FORA ComfortScan Ear Thermometer

Indications for Use:

The Fora ComfortScan Ear Thermometer is an electronic thermometer using an infrared sensor to detect human body temperature from the ear canal on people of all ages for home and professional use.

Prescription Use \_\_\_\_\_  
(21 CFR Part 801 Subpart D)

And/Or Over the Counter Use  X   
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Red C Chyn 6/6/12

Division Sign-Off

Office of Device Evaluation (ODE)

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